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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,295	02/17/2006	Stephen J. Brand	24492-011 NATL	8771

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EXAMINER	
STOICA, ELLY GERALD	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
07/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,295	BRAND ET AL.	
	Examiner	Art Unit	
	Elly-Gerald Stoica	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,9,10,13,16,17,19,21,32,47,48,91,92,98,101 and 108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5,9,10,13,16,17,19,21,32,47,48,91,92,98,101 and 108* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, 9, 10, and 101, drawn to a method for treating diabetes.

Group II, claim 5, drawn to a method of treating diabetes involving ex vivo treatment of cells.

Group III, claim 13, drawn to a method of inducing proliferation of pancreatic islet cells.

Group IV, claims 16, 17, 19, 47-48, 92, and 98, drawn to a composition comprising a Gastrin/CCK receptor ligand.

Group V, claims 21, 91, 108, drawn to a method of expanding stem cells.

Group VI, claim 32, drawn to a method for reducing an amount of stem cells.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: methods of treating diabetes using Gastrin/CCK receptor ligand were known in the art as well as compositions containing it (Brand SJ, WO/02055152; Kim et al. U.S. Pat. 6,284,727).

Each of the methods of inventions I-III and V-VI is different in design and function from each other and the composition of invention IV is related to the methods of inventions I-III and V-VI as product and method of use but the methods can be performed with different compositions from the composition of Invention IV.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a Glucagon-like peptide 1 receptor ligand (either GLP-1 or exendin-4);
- a Glucagon-like peptide 2 receptor ligand;
- a gastric inhibitory polypeptide (GIP) receptor ligand;
- a keratinocyte growth factor (KGF) receptor ligand;
- a dipeptidyl peptidase IV inhibitor;
- a REG protein receptor ligand; a Growth Hormone receptor ligand;
- a Prolactin (PRL) receptor ligand;
- an Insulin-like Growth Factor (IGF) receptor ligand;
- PTH-related protein (PTHrP) receptor ligand;
- hepatocyte growth factor (HGF) receptor ligand;
- a bone morphogenetic protein (BMP) receptor ligand;
- a transforming growth factor-β (TGF-β) receptor ligand;
- a laminin receptor ligand;
- vasoactive intestinal peptide (VIP) receptor ligand;

- a fibroblast growth factor (FGF) receptor ligand;
- a keratinocyte growth factor receptor ligand;
- a nerve growth factor (NGF) receptor ligand;
- an islet neogenesis associated protein (INGAP) receptor ligand;
- an Activin-A receptor ligand;
- a vascular endothelial growth factor (VEGF) receptor ligand;
- an erythropoietin (EPO) receptor ligand;
- a pituitary adenylate cyclase activating polypeptide (PACAP) receptor ligand;
- a granulocyte colony stimulating factor (G-CSF) receptor ligand;
- a granulocyte-macrophage colony stimulating factor (GM-CSF);
- a platelet-derived growth factor (PDGF) receptor ligand;
- a growth hormone;
- a Secretin receptor ligand.

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

The whole list, less the GLP-1 or exendin-4 or the growth hormone, correspond to claims 1-2, 5, 9-10, 13, 16, 17, 19, 21, 32, 47-48, 91, 92, 98, 101, and 108.

GLP-1 or exendin-4 correspond to claim 3 and growth hormone corresponds to claim 4.

The following claims are generic: 1, 5, 16, and 32.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they have different structures and physico –chemical properties and were all known in the art.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.